FEB 2 1 2013

DetachaTip® III Plus Multi-Use Instrument Tray

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92 for 510(k) number K123175 as of January 8, 2013.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502
Establishment Registration Number: 1320894

B. Company Contact

Anna D'Lima, RAC
Regulatory Affairs Specialist
ConMed Corporation
525 French Road
Utica, NY 13502
Phone: 315-624-3439
Fax: 315-624-3225
e-mail: annadlima@conmed.com

C. Device Name

Trade Name:	DetachaTip® III Plus Multi-Use Instrument Tray
Common Name:	Instrument Tray/Sterilization Tray,
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes, and other Accessories
Regulation Number:	21 CFR 880.6850 Class II KCT
Panel:	General Hospital and Personal Use Devices

D. Predicate Device Name

ConMed DetachaTip® Instrument Tray
ConMed Corporation
510(k) K092414

E. Device Description

The ConMed DetachaTip® III Plus Multi-Use Instrument Tray (REF 3-4343) is used to retain reusable instruments during steam sterilization. The tray consists of a perforated tray base and lid made from polyphenylsulfone (Radel®). Latches securely hold the tray lid to the tray base, and handles are provided for transportation. A perforated silicone mat protects instruments placed in the bottom of the tray. A Radel® instrument rack separates and secures the DetachaTip® III instruments throughout sterilization processing and/or storage. The tray is not intended to maintain sterility. The instrument tray is to be used with an FDA cleared sterilization wrap.

DetachaTip® III Plus Multi-Use Instrument Tray is designed to fit a standard autoclave, comprised of materials resistant to corrosion, and able to withstand repeat steam sterilization cycles. The tray is designed to withstand repeated use. It is not designed to be serviced or repaired. The materials comprising the tray are biocompatible and will not contaminate reusable medical devices.

Radel® is a registered trademark of Solvay Advanced Polymers

F. Intended Use/ Indications for Use

DetachaTip® III Plus Multi-Use Instrument Tray (REF 3-4343) is a reusable sterilization tray intended for pre-vacuum steam sterilization, organization, transportation, and storage of enclosed, reusable medical devices. DetachaTip® III Plus Multi-Use Instrument Tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated FDA cleared sterilization wrap in order to maintain sterility of the enclosed medical instruments.

DetachaTip® III Plus Multi-Use Instrument Tray is intended for use with DetachaTip® III instruments and ConMed reusable medical devices meeting challenge conditions defined in Table 1. The MAXIMUM recommended load is: 25 lb [11.3 kg].

Table 1 – Reusable Medical Device Challenge Conditions

Minimum Inner Diameter	**Maximum** Length
5 mm	45 cm
3 mm	32 cm

Sterilize the DetachaTip® III Plus Multi-Use Instrument Tray using the following parameters:

Method	Cycle	Temperature	Exposure Time	Dry Cycle Time
Steam (wrapped)	Pre-vacuum	270°F(132°C)	4 minutes	30 minutes
The devices should be sterilized using an FDA cleared wrap indicated for these sterilization cycles. Allow for a 30 minute cool down prior to handling.				

H. Performance Data

DetachaTip® III Plus Multi-Use Instrument Tray meets requirements of ANSI/AAMI ST77:2006/(R)2010 *Containment devices for reusable medical device sterilization.* Based on the nonclinical performance testing, the subject device is as safe and effective as the legally marketed predicate device.

I. Substantial Equivalence

The DetachaTip® III Plus Multi-Use Instrument Tray and predicate device are substantially equivalent in intended use, device design, materials, performance, effectiveness, and safety. The proposed device and the predicate device are containment devices for sterilization of reusable medical devices using steam sterilization by healthcare providers. The proposed device presents no new issues of safety and efficacy. Note: Prior designs of DetachaTip® instruments shall not be used in the DetachaTip® III Plus Multi-Use Instrument Trays.

Feature	**DetachaTip® III Plus Multi-Use Instrument Tray**	**ConMed DetachaTip® Instrument Tray**
	K123175	**K092414**
Model #/ REF	3-4343	1-4327
Description	Containment devices for sterilization of **DetachaTip® III Instruments** and **ConMed reusable medical devices meeting challenge conditions defined in Table 1** using steam sterilization by healthcare providers. The device should be used only in conjunction with FDA cleared wrap indicated for the sterilization cycles.	Containment devices for sterilization of **DetachaTip® II Instruments** using steam sterilization by healthcare providers. The device should be used only in conjunction with FDA cleared wrap indicated for the sterilization cycles.
Sterilization Method	Pre-vacuum steam sterilization	Same
Materials	Polyphenylsulfone (Radel), Silicone, Stainless Steel	Same
Device Design	**Four part instrument tray** 1) Tray lid 2) Inner tray includes **10 wells** for **DetachaTip® III Instruments** and **4 wells for DetachaTip® III Handles** 3) Silicone mat 4) Tray base for **ConMed reusable medical devices meeting challenge conditions defined in Table 1**	**Four part instrument tray** 1) Tray lid 2) Inner tray includes **10 wells** for **DetachaTip® II Instruments** 3) Silicone mat 4) Tray base for **DetachaTip® II Handles**
Performance Testing	ANSI/AAMI ST77:2006/(R)2010 *Containment devices for reusable medical device sterilization*	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2013

Ms. Anna D' Lima, RAC
Regulatory Affairs Specialist
ConMed Corporation
525 French Road
UTICA NY 13502

Re: K123175
Trade/Device Name: DetachaTip® III Plus Multi-Use Instrument Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: January 8, 2013
Received: January 11, 2013

Dear Ms. D' Lima:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

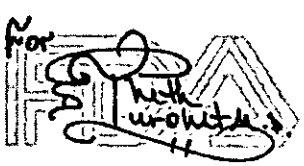
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123175

Device Name: DetachaTip® III Plus Multi-Use Instrument Tray

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Table 1 – Reusable Medical Device Challenge Conditions	
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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123175